Providing safe blood banking in sub-Saharan Africa

An analysis of the blood transfusion services at a district hospital in Malawi

An observational study conducted at Mangochi District Hospital, Malawi

by

Nils Christian Tvedt Karlsen
Nikolai Wexels

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Faculty of Medicine, University of Oslo
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Supervisors:
Peter Jourdan, Department of Infectious Diseases,
OUH and Faculty of Medicine, UiO, Norway

Borghild Roald, Department of Pathology,
OUH and Faculty of Medicine, UiO, Norway

Abstract

Background

Important efforts are made to organise sustainable, efficient and safe blood transfusion services in sub-Saharan Africa. Still, the adequate supply of safe blood products remains largely insufficient in this area. In this study, we analyse the quality and capacity of the equipment and technical procedures at a hospital based blood transfusion service in rural Malawi.

Material and methods

The study was performed at Mangochi District Hospital in southern Malawi in December to January 2010. We observed and registered the presence and use of the equipment, test reagents, procedures, quality control for screening for infectious agents and storage of blood products. The services were evaluated according to WHO guidelines. For additional details, the Malawi Blood Transfusion Service (MBTS) guidelines were consulted.

Results

During the observation period, a total of 280 units of blood were analysed and applied for transfusion at the hospital. The investigators observed twenty complete series of laboratory analyses of blood examined for transfusion. The equipment, test reagents, procedures, quality control of the transfusion services in this district hospital laboratory meet the main criteria for an adequate WHO stage of development.

Conclusion

The findings indicate that blood transfusion services adapted to local conditions might be a sustainable solution for safe blood transfusion services in sub-Saharan Africa. Further and larger studies are needed to confirm these findings, and to explore other aspects required to maintain sustainable and safe blood transfusion services in economically limited settings.

CONTENTS

INTRODUCTION

Severe malarial anaemia and pregnancy-related haemorrhage are major causes of child and maternal mortality in sub-Saharan Africa[1]. More than 20 per cent of childhood mortality is attributed to malarial anaemia, and more than 30 per cent of maternal mortality is due to pregnancy-related haemorrhage[2,3]. Studies indicate that the quality and capacity of blood transfusion services directly affect mortality rates[4-6].

Reports indicate that 40 per cent of African World Health Organization (WHO) member states have reached the regional objective of 80 % voluntary, non-remunerated blood donations[7]. However, the adequate supply of safe blood products remains largely insufficient in sub-Saharan Africa, and important efforts are still made to organise sustainable, efficient and safe blood transfusion services[8-11].

Few studies have explored the sustainability of blood transfusion services in Sub-Saharan Africa, neither with regards to the quality nor the capacity over time according to international guidelines[12-14]. This study reports the status of the blood transfusion service at a district hospital in Malawi five years after implementation of a centralised system[15]. The aims of the study are to analyse the quality and capacity of the equipment and technical procedures according to WHO guidelines[11].

MATERIAL AND METHODS

Study area

The study was performed at Mangochi District Hospital in southern Malawi in December to January 2010. The hospital is situated at the southern tip of Lake Malawi (Figure 1), and is the referral hospital for more than half a million inhabitants. The hospital comprises 240 beds in one paediatric ward and two separate wards for women and men.

Picture 1. Mangochi District Hospital in Malawi.

The medical staff includes 1 medical doctor, 8 clinical officers, and 30 nurses. Annually, the hospital treats approximately 150 000 patients (Bendabenda, personal communication). The prevalence of human immunodeficiency virus (HIV) infection in Malawi has been estimated to 11 per cent[16] and the Mangochi district is subject to perennial malarial transmission rates[17].

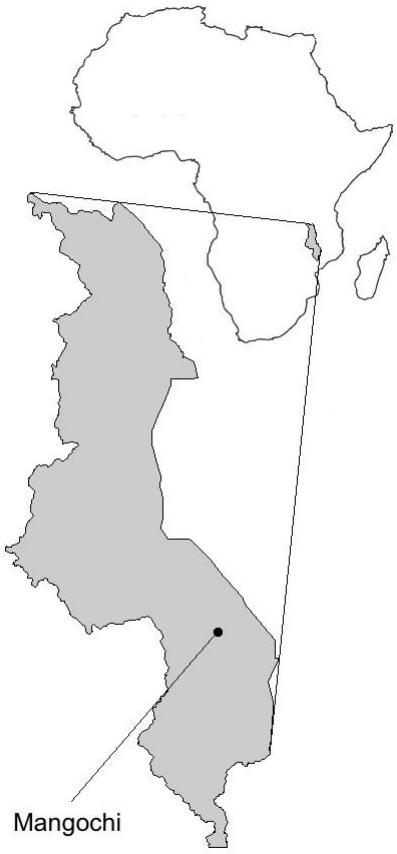

Figure 1. Location of Mangochi District Hospital in Malawi.

Mangochi blood transfusion services

The blood transfusion services at Mangochi District Hospital are part of the hospital's general laboratory services. The laboratory equipment, procedures and quality control follow the Essential Medical Laboratory Services (EMLS) guidelines developed by the Ministry of Health and Population between 1998 and 2002[18]. In 2000, the national Malawi Blood Transfusion Services (MBTS) was established to govern the blood transfusion services at Mangochi District Hospital.

At present, the laboratory is governed by a director, and employs seven laboratory technicians and assistants. Annually, the blood transfusion services receive, analyse and deliver

approximately 3 200 units of blood (Chisuwo, personal communication). Figure 2 shows a schematic figure of the laboratory premises.

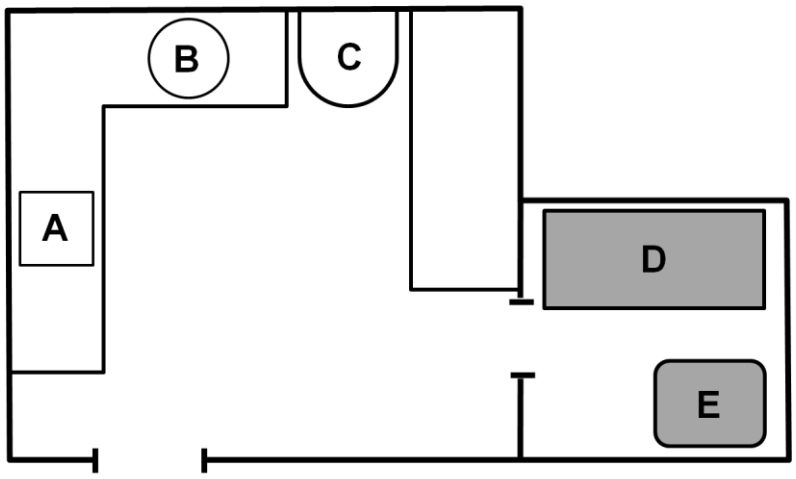

Figure 2. Schematic figure of the laboratory premises.

A: Laboratory microscope, B: Thermo Scientific Heraeus® Labofuge® 200, C: Sink, D: Deep freezer, E: Sanyo Blood Bank Refrigerator.

Picture 2. From the laboratory premises

Registration procedures

The study was conducted by two specifically trained medical students (NCK and NW) who observed and registered the presence and use of the equipment, test reagents, procedures and quality control; for screening of infectious agents, ABO and RhD blood grouping, cross matching and storage of blood products. The services were evaluated according to the recommendations for a WHO basic adequate stage of development (Table 1)[11]. For additional details, the MBTS guidelines were consulted. All registrations were cross-checked by the investigators. Donor recruitment, recipient administration and monitoring were not included in this study.

Ethical considerations

The study was granted ethical permission by the ethical committee of Mangochi District Hospital. The study did not have any consequences for patient care or treatment. All registered observations were of laboratory technical character, and no patient data were included in the study.

RESULTS

During the observation period, a total of 280 units of blood were analysed and applied for transfusion at the hospital. The investigators observed twenty complete series of laboratory analyses of blood examined for transfusion.

General procedures

When blood transfusion was required for one of the hospital's patients, an ethylene diamine tetraacetic acid (EDTA) tube containing the recipient's blood was sent to the laboratory attached to a blood transfusion request form. The blood sample and form were labelled with the date and the recipient's name and ward. The results of the grouping of the recipient's blood and cross matching results were recorded on the blood transfusion form.

Blood from a potential donor was drawn to fill an EDTA tube and a blood unit bag equipped with a donor identification number, the current date and the estimated expiry date. The blood in the EDTA tube was used for measuring the haemoglobin (Hb) (HemoCue Hb 201), and for screening, grouping and cross-matching. The results were recorded in a designated laboratory log book of blood transfusions. The blood to be transfused originated from a previous donation by a volunteer donor, or was drawn from a relative of the patient at the time of transfusion. During our study time 53% of the transfused units originated from voluntary donors, and 47% of the units were donated by relatives of the patient (manuscript submitted).

Screening for transmissible infectious agents

Following free and informed oral consent, the donor's blood was screened for transmissible infectious agents. To ensure anonymity, a donor identification number was assigned and used for identification of test tubes, results and blood products. Patient names and identification numbers

were kept in the designated laboratory log book. The donor's blood from the original EDTA tube was screened for HIV 1/2, hepatitis B virus, hepatitis C virus and syphilis using rapid tests (Table 2). Microscopic screening for malarial parasites was not performed routinely, and the indications for doing so were not clear-cut. If one or more of the screening tests were to come out positive, the blood would be discarded. The donor was assured appropriate counselling and follow-up by the hospital's medical staff.

Blood grouping

Table 3 shows the equipment, test reagents, procedures and quality control of blood grouping. Blood grouping was performed using whole blood. In the case of inconclusive results, a three per cent red cell suspension was used. ABO grouping was performed by adding one drop of the respective anti-sera to one drop of blood on a test tile (forward grouping). The blood and anti-sera were carefully mixed together and analysed for agglutination or haemolysis against a white background. The donor plasma was not tested for ABO antibodies (reverse grouping), and no parallel testing was performed.

Cross matching

In order to avoid serious transfusion reactions, a major cross match without the use of Anti Human Globulin (AHG) reagent (Coombs) was performed[11]. The donor's red blood cells were centrifuged with physiological saline to make a three per cent red cell suspension. One drop of donor's red blood cell suspension was mixed with three drops of the recipient's plasma in a test tube. The test tube was centrifuged for one minute and thereafter checked for agglutination.

If the cross-matching was negative, the recipient's name was copied from the blood transfusion form to the label of the blood bag, and the product number and estimated expiry date were

transferred from the blood bag to the transfusion form. Finally, the blood transfusion bag was attached to the transfusion request form and returned to the ward. The equipment, reagents, procedures and quality control for cross matching are shown in Table 4.

Storage of blood units

Table 5 gives an overview of the equipment and procedures for storage of blood units. The laboratory was equipped with a refrigerator and a separate deep freezer used to produce and store ice for transportation of blood units to the hospital. The refrigerator was controlled manually and by automatic control systems, and the temperature was recorded daily on an MBTS-approved temperature monitoring form attached to the refrigerator. The laboratory was assured continuous electricity by an aggregate.

Blood samples that had not completed testing were kept in a separate part of the refrigerator. The blood units were stored according to blood types and kept up to 35 days at a temperature from 2 to 6^{o} Celsius, and were stirred three times per week. Blood units older than 35 days and units kept outside of the refrigerator for more than one hour were discarded. Only whole blood was produced and kept at this hospital.

DISCUSSION

The supply of safe blood products remains largely insufficient in sub-Saharan African countries, and sustainable and efficient ways of organising and maintaining safe blood transfusion services are needed[8-10,19]. The findings in this study suggest that a district hospital may organise safe and sustainable blood transfusion services. The equipment, test reagents, procedures and quality control of this district hospital laboratory meet the main criteria for an adequate WHO stage of development[11]. Reports suggest that western models for blood transfusion services may not be applicable in economically restricted countries, and alternative models adapted to local conditions have been discussed[8,10,14].

The transfusion services at this hospital use highly sensitive and specific rapid tests for screening of transfusion transmissible infections. However, the risk of infections, including HIV, remains a serious challenge[11,20]. The risk of transmissible infections may be reduced by improving the safety of and access to blood units, by recruiting non-remunerated voluntary donors, and by reducing blood transfusions as emergency, last resort treatment of critically ill patients[8,14,21]. Moreover, pre-donation screening may reduce avoidable costs of relatively expensive blood bags[8].

There is a paucity of data concerning the potential clinical consequences of blood transfusions with malaria-infested blood[22]. Affordable and sustainable methods for routine blood screening in economically restricted countries are needed to prevent possible occurrence of malaria to blood recipients[22]. However, in the WHO guidelines, screening for malaria is not an absolute requirement for a basic adequate level of blood transfusion services[11].

Forward grouping was routinely performed in accordance with WHO guidelines to prevent potential antibody reactions to donor RBCs[23]. Reverse grouping, however, was not performed at this laboratory, thus reducing the quality assurance of the ABO grouping[24]. However, this was compensated for by the consequent use of cross matching prior to transfusion.

A major crossmatch may confirm the findings of the blood grouping, but might omit the potential detection of atypical or unexpected antibodies other than anti-A and anti-B in the recipients' sera[24]. Few studies have explored the frequency and characteristics of blood transfusion reactions in resource-limited settings[25], however, it is probable that measures to improve precise blood grouping and crossmatching could reduce the risk of serious transfusion reactions.

Approximately 3.5% of Malawians are Rh-D negative and the consideration of iso-immunisation is especially important in women of reproductive age[23,26]. Multiparity is common in Malawi, however, there are few reports of haemolytic disease of the newborn[24]. The use of approved anti-D reagents at Mangochi District Hospital could permit the use of anti-D prophylaxis as a cost-efficient measure[27]. However, anti-D prophylaxis remains a challenge for blood transfusion services and clinicians, and may not be feasible at a basic adequate level[28].

Available basic equipment and adequately trained laboratory staff are important for sustainability and quality of blood transfusion services[8,29]. Updated and physically available guidelines are simple and important measures to meet WHO guidelines for technical procedures[11]. Detailed and updated guidelines were not fully available at this district hospital due to lack of paper and printing options.

Increased funding alone may not necessarily increase the level of development of hospital-based blood transfusion services in the long term. Appropriate measures should be implemented gradually, and qualified health professionals should be capable of sustaining the measures over time[29]. The blood transfusion services analysed in this study employed an educated staff, and an experienced laboratory manager supervised the procedures to ensure the quality. Regular clinical meetings and strict supervision by senior medical staff were, alongside implementation of guidelines, identified as vital factors to reduce avoidable blood transfusions[29].

It is possible that only small investments, such as easily available prints of guidelines or the use of AHG could be cost-efficient measures to improve quality of the blood transfusion services and the disability adjusted life years (DALYs) at this district hospital[27]. As shown in Figure 3, even small interventions may be cost-effective. Nearly two thirds of African WHO member states report that they have a centralised system for data collection and analysis to ensure quality management[7,30]. Quality control procedures of the blood transfusion services at this hospital could still be improved, and are important to ensure for the safety of blood transfusions[18,31,32].

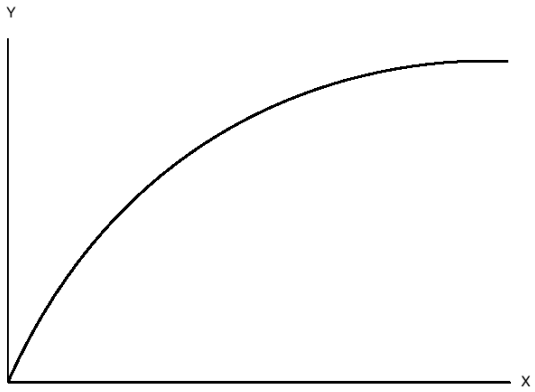

Figure 3. Positive health effects of total technology costs in transfusion service.

A simplified graph showing positive health effects (y-axis) as a function of the total technology costs (x-axis).

The study has several limitations. The study was performed over a relatively limited period of time in a country which recently has received funds for the development of centralised blood transfusion services[15]. The investigators sought to remain objective and unbiased in their observations; however, they may have been influenced by the local staff and circumstances. The laboratory staff, on their hand, may have been affected by their awareness of the objective of the study. This study was limited only to the laboratory services of the blood transfusion services. We have reported on the administration and distribution of transfusions at the hospital in a parallel study (manuscript submitted).

In conclusion, the findings suggest that sustainable blood transfusion services may be organised at a district hospital level to assure safe and adequate access to blood products. The equipment, test reagents, procedures and quality control of this district hospital transfusion services meet the main criteria required for a basic adequate WHO stage of development. The findings indicate that blood transfusion services adapted to local conditions might be a sustainable solution for safe blood transfusion services in sub-Saharan Africa. Further and larger studies are needed to confirm these findings, and to explore other aspects required to maintain sustainable and safe blood transfusion services in economically limited settings.

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CONFLICTS OF INTEREST

None declared.

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Table 1. WHO stages of development.

[a]Screening of transmissible infectious agents, [b]Whole blood, [c]ABO blood group system, [d]Red blood cells, [e]Hepatitis-B-virus surface antigen, [f]Human immunodeficiency virus type 1 and 2, [g]Others as defined in national blood policy, [h]Rhesus blood group system, [i]Anti-human globulin

Stage of development	Blood products	Screening[a]	Blood grouping	Cross matching	Storage
1. Inadequate	WB[b]	None	ABO[c]	None or slide, room temp.	Not controlled
2. Basic adequate	WB RBC[d]	Syphilis HbsAg[e] HIV-1/2[f] Others[g]	ABO RhD[h] - tube or - microplate	Major 37°C (AHG[i])	Controlled
3. Basic full-range	WB, RBC (0-30%) Plasma Platelets Cryoprecipipitate	As in 2	As in 2, plus antibody screening (donor)	As in 2, plus antibody screening (patient)	As in 2
4. Highly productive	As in 3, plus RBC (30-100%) using additive solutions	As in 2	As in 3	As in 3	As in 2
5. Advanced	As in 4, plus frozen RBC, washed RBC, special products,	As in 2	As in 3	As in 3	As in 2

	cytapheresis				
6. Sophisticated	As in 5, plus automation, computers, plasma fractionation, basic research etc.				

Table 2. Screening for transmissible infectious agents.

[a]Sensitivity 0.98, spesificity 1.0, [b]Sensitivity 0.95, spesificity: 1.0, [c]Sensitivity 0.92, spesificity 1.0, [d]indications for screening not clear, [e]Hepatitis-C-virus, [f]Sensitivity 0.94, spesificity 1.0, [g]Inverness Medical Innovations inc, [h]Standard Diagnosis inc.

	WHO guidelines	**Mangochi District Hospital**
Procedures	Screening for HIV, HBV, syphilis and malaria	Screening for HIV 1/2, HBV, HCV, syphilis (and malaria)
Test reagents	Rapid test HIV	Determine®[g]HIV 1/2[a]
	Rapid test HBV (HBsAg)	Determine®[g]HBsAg[b]
	Rapid test syphilis	Determine®[g]Syphilis TM[c]
	Microscopy of thick blood film for malaria	Not routinely performed[d]
		SD Bioline[h] HCV[e,f]
Quality control	Labelling with ID number	Performed
	Immediate registration of results	Performed

Table 3. Blood grouping.

	WHO guidelines	Mangochi District Hospital
Procedures	Forward and reverse grouping (Red cell grouping)	Forward grouping (Whole blood as standard)
Equipment	Test tubes/grouping tiles	BD Vacutainer®
	Applicator stick	Available
	Centrifuge	Thermo Scientific Heraeus® Labofuge® 200
Reagents	Use of approved anti-A, anti-B, anti-AB and anti-D reagents	Närulä Exports
Quality control	Labelling with name or number	Performed
	Immediate registration of results	Performed
	Discard expired reagents	Not observed
	Cross-check results by a second person	Not performed
	Guidelines available in laboratory	Incomplete edition available

Table 4. Cross matching.

	WHO guidelines	Mangochi District Hospital
Procedure	Major with Coombs	Major without Coombs
Equipment	Test tubes/grouping tiles	BD Vacutainer®
	Centrifuge	Thermo Scientific Heraeus® Labofuge® 200
	Water bath	Not available
	Saline 0,9%	Missionpharma
Reagents	Anti-human globulin (AHG) reagent	Not available
	IgG sensitised cells	Not avaiable
Quality control	Labelling with ID number	Performed
	Immediate registration of results	Performed
	Discard expired reagents	Not observed
	Discard expired/haemolysed blood units	Not observed
	Cross-check results by a second person	Not performed
	Guidelines available in laboratory	Complete edition available

Table 5. Storage of blood units.

A: From MBTS guidelines.

	WHO guidelines	Mangochi District Hospital
Equipment	Blood collection bags	Medikit® Medibag 450 mL Jierui Blood Bag 450 mL HL Haemopack 230 mL
	Appropriate storing device	Sanyo Blood Bank Refrigerator
	Thermostatically controlled blood bank refrigerator with alarm	Available
	Additional thermometer	Available
	Thermograph charts	Available
	Deep freezer	Available
Quality control	Maximum storage time five weeks[A]	Not observed
	Recording of daily temperature readings	Performed
	Non-tested blood stored separately	Performed
	Discard room tempered blood >1 hour	Not observed
	Blood units stirred three times a week	Performed
	Discard expired blood units	Performed
	Guidelines available in laboratory	Incomplete edition available